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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,551	10/02/2003	Michael Robert Barbachyn	01337.US1	9537

25533 7590 10/28/2004

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EXAMINER

HABTE, KAHSAI

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 10/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/677,551	Applicant(s) BARBACHYN ET AL.	
	Examiner Kahsay Habte, Ph. D.	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 19-29 is/are rejected.
- 7) ☒ Claim(s) 17,18 and 30 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/12/2004</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

1. Claims 1-30 are pending.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claims 1-30, drawn to [1,4]oxazino compounds (i.e. variable X in formula I is -C-O-C-), classified in class 544, subclasses 71 and 101.
 - II. Claims 1-30 (in part), drawn to [1,4]piperazino compounds (i.e. variable X in formula I is -C-N-C-), classified in class 544, subclass 344.
 - III. Claims 1-12 (in part), 15-17 (in part) and 19-30 (in part), drawn to others, classified in classes 540, 544, 546 and 548, subclass various.

The inventions are distinct, each from the other because of the following reasons: Groups I-III are directed to structurally dissimilar compounds such that the variable core created by the varying definitions of X in formula I do not belong to the same recognized class of chemical compounds in the art, and references anticipating one invention, would not render obvious the others. Group I is drawn to tricyclic [1,4]oxazino compounds and is different from Groups II-III, since the core structure contains oxygen and nitrogen in the core structure. Group II is drawn to a tricyclic [1,4]piperazino compounds and is different from Group I or Group III, since it has two nitrogens in its core structure. Group III is drawn to others (e.g. a tricyclic [1,4]thiazino compounds, a tricyclic diazepino compounds, a tricyclic thiazolo compounds, etc.) and is different from

the compounds of Groups I-II, since the core structure contains different heteroatoms (e.g. N and S) or just carbon atoms of different chain length in its core structure. Thus, separate searches in the literature as well as in the U.S. Patent Classification System would be required. Each group's compounds are made and used independently of each other and could support separate patents. The compounds differ significantly in chemical structures. One skilled in the art would not consider such diverse structure equivalents of each other.

Because these inventions are distinct for the reasons given above and have acquired separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. Steve Young on October 27, 2004 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-30. Affirmation of this election must be made by applicant in replying to this Office action.

3. The claims are drawn to multiple inventions for reasons set forth in the restriction requirement. The claims are examined only to the extent that they read on the elected invention. Cancellation of the non-elected subject matter is recommended in response to this Office Action. It is also recommended that applicants delete non-elected species from claims 17-18 and 30.

Abstract

4. The abstract's content fails to enable the reader thereof, regardless of his or her degree of familiarity with the patent documents, to quickly ascertain the character of the subject matter covered by the technical disclosure and fails to include that which is new in the art to which the invention pertains. There is no chemical structure or exact nomenclature of the compounds that applicants are claiming. Applicants have to draw the chemical structure of formula I to overcome this objection.

Objection

5. Claims 17-18 and 30 are objected to as being drawn to multiple invention, but would be allowable if the non-elected invention are removed.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 20 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of microbial infections specifically for bacterial infection, does not reasonably provide enablement for the treatment of microbial infection generally. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. There has been recited a method

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for the treatment of microbial infection in general, but the specification is not enabled for such a scope.

There is no such agent, which can treat all microbial infection generally. Microbial infections are extremely broad. Some microbial infections are caused by bacteria (i.e. meningitis, whooping cough, tetanus, syphilis, etc.), some are caused by virus (i.e. HIV, common cold, measles, chicken pox, etc), some are caused by fungus (i.e. athletic foot, etc.), some are caused by protozoa (i.e. Amebiasis, Giardiasis, Leishmaniasis, Beaver fever, Toxoplasmosis, Trichomoniasis, etc.). Not only that the viral diseases are different from bacterial and fungal diseases, but the viral diseases as listed above are also different one from the other. The nature of effect, origin, symptom, incubation, diagnosis, etc., is different one from the other. The same is true for the bacteria caused diseases and fungal caused diseases. For example, HIV (human immunodeficiency virus) is a human T-cell leukemia/lymphoma virus of the subfamily Lentivirinae that is the causative agent of the disease AIDS. AIDS is an acquired immunodeficiency syndrome, an epidemic retroviral disease due to infection with human immunodeficiency virus (HIV-1), transmissible via blood or semen, and characterized by an ineffective immune response; the disease follows a protracted and debilitating course and has a poor prognosis.

According to the specification on pages 1 and 24-25, applicants' compounds are disclosed to have an antibacterial activity. Applicants can overcome the rejection, by limiting their invention to the treatment of bacterial infection.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16 and 19-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a. In claim 1 or elsewhere in the claims, the phrase "Each R³ is independently(d) C₁₋₇ alkyl which is optionally partially unsaturated" is incorrect. An "alkyl" or "cycloalkyl" group is already a saturated group and cannot be partially saturated. Like wise, the same rejection applies for "C₃₋₈ cycloalkyl" in claim 1 (line 29).

b. In claim 1, the phrase "including enantiomeric, diastereomeric, or tautomeric isomers" is not clear. Since applicants are claiming compounds of formula I that is broader and includes all said isomers, the recitation of said phrase is redundant. It is recommended that applicants delete said phrase from claim 1.

c. In claim 3, the phrase "Each R^3 is independently(c) Oxo" is not clear. Variable R^3 is a monovalent, but substituents such as "oxo" are divalent. Note that only one oxo group (=O) is permitted on the tricyclic ring.

d. In claim 13, there is no period after the end of the claim.

e. In claim 19, there are two periods in the claim. Applicants have to remove the first period after $ZnCl_2$ to overcome the rejection.

f. In claim 25, the composition lacks carrier.

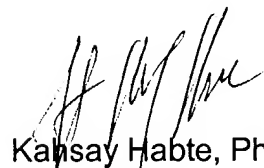
Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte, Ph. D. whose telephone number is (571) 272-0667. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on (571) 272-0674, if there is no reply within 24 hours, James Wilson (Acting SPE) can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kalsay Habte, Ph. D.
Examiner
Art Unit 1624



Mark L. Berch
Primary Examiner
Art Unit 1624

KH
October 27, 2004